REMARKS

Declaration

Attached is a new Combined Declaration and Power of Attorney executed by Victor A. Morris, the heir of the deceased inventor Sharon D. Smith. Sharon D. Smith died intestate. Thus, Victor A. Morris, her spouse, and Ryan Morris, her daughter, are her heirs under Connecticut intestacy law. Ryan Morris is a minor, and therefore, did not execute the declaration.

Status of the Claims

Claims 1, 3-23, 25-27, 29, and 31-42 are pending in the current application. Claims 2, 24, 28 and 30 have been canceled without prejudice or disclaimer of the subject matter claimed therein. Claims 1, 3, 5, 17, 22, and 25-27 have been amended. The amendments to the claims supply separate specific embodiments of the claimed invention.

Applicants thank the Examiner for rejoining the claims of Group I with the claims of Group II. Thus, claims 1, 3-23, 25-27, 29, and 31-42 are examined in the current application.

Amendments to the Claims

The amendments to claims 1, 5, 17, 22, and 25-27 do not introduce prohibited new matter. Support for the amendment to claims 1, 5, 17, and 25-27 can be found in paragraph [0099] line 7. Support for the amendment to claim 22 can be found in paragraph [0085], line 1.

Rejections of the Claims Under 35 U.S.C. § 112, Second Paragraph

Claims 22, 25-27, and 32-40 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite.

It appears that the Office Action inadvertently left out claims 5 and 17, since they were also rejected.

Claim 5 has been amended to recite what "CIS" stands for.

Claim 17 has been rejected as being indefinite for reciting "agent." The term "agent" is defined in paragraph [0042] of the specification. The MPEP states that if the scope of the subject matter embraced by the claim is clear, then the claims comply with 35 U.S.C. § 112, second

paragraph. (MPEP 2173.04) Further, breadth is not indefiniteness. (MPEP 2173.04) Thus, the term "agent" which is defined in the specification is not indefinite. Unlike *Ex Parte Tanksley*, cited in the Office Action, the term "agent' in claim 17 is defined in the specification and is therefore definite.

Claim 22 has been rejected as being vague and indefinite for reciting "a means to analyze the presence of survivin." Claim 22 has been amended to replace "means" with "component." Examples of various components are disclosed in paragraph [0085]. Thus, claim 22 as amended is not vague and indefinite.

Claims 25-27 are vague and indefinite because the claimed methods lack complete steps. Claims 25-27 as they stand include two steps. The first step comprises quantitating the amount of survivin in a sample of urine supernatant from a patient, and the second step comprises comparing the amount of survivin in the sample. Accordingly, the claims recite a detection step (step 1) and a comparing step (step 2). Further, the claims include the required reagent which is the sample of urine supernatant. The claims also require reagents for quantitating the amount of survivin. Reagents that detect survivin are described in the specification and include those that interact with survivin or the nucleic acid encoding survivin. Accordingly, the claims recite the required steps and reagents.

Rejection of the Claims Under 35 U.S.C. § 112, First Paragraph

A. Claims 17 and 21-24 are rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification to enable the skilled artisan to make and/or use the invention.

Claim 24 has been canceled without prejudice or disclaimer of the subject matter claimed therein. Thus, rejection of claim 24 is deemed moot.

The Office Action alleges that given the breadth of the claims, the limited guidance in the art, and the unpredictability of the art, there is no reasonable expectation of success in practicing the claimed invention. It seems that the Office Action is rejecting the claims based on scope rather than written description.

Nevertheless, the specification provides sufficient description for and enables the breadth of the subject matter in claims 17 and 21-23. As stated in the Office action, the specification

provides agents that may be used for detecting survivin. The specification describes the term "agent" as any molecule that interacts with survivin or the nucleic acid encoding survivin. The specification provides sufficient examples of such agents, including survivin antibodies, survivin binding partners, and nucleic acids encoding survivin and teaches how to obtain and use these agents on pages 11-20. The specification also teaches how to detect and quantitate survivin and how to compare the results for diagnosing, prognosing, and for monitoring cancer. The Examples provide specific guidance for making and using the agents for diagnosing, prognosing, and monitoring cancer, and the detecting and quantitating of survivin in a sample of urine supernatant is not unpredictable given these teachings.

The claims as they stand are directed to kits for diagnosing, prognosing, and monitoring cancer. Respectfully, given the teachings of the specification and given the sufficient description of the claimed invention, the guidance for making and using the claimed invention, and the predictability of quantitating and detecting survivin, the claims do not lack written description and are enabled by the specification.

Rejections of the Claims Under 35 U.S.C. § 102

A. Claims 1-4, 6-10, 13, 15, 16, 28-34, and 41 are rejected under 35 U.S.C. § 102(b) as being anticipated by Jouben-Steele *et al.*

Claims 2, 28, and 30 have been canceled without prejudice or disclaimer of the subject matter claimed therein. Thus, the rejection of claims 2, 28, and 30 is deemed moot.

Claim 1, as amended, is directed to a method of diagnosing cancer in a patient comprising assaying a sample of urine supernatant for the presence or absence of survivin. Claims 2-4, 6-10, 13, 15, 16, 29, 31-34, and 41 ultimately depend from claim 1. The cited reference, Jouben-Steele *et al.*, does not disclose diagnosing cancer comprising assaying a sample of urine supernatant for the presence or absence of survivin. Rather, the cited reference discloses assaying urine sediments, *i.e.,* cell material, for the presence of survivin. Urine sediments and urine supernatant are distinct urine samples. Accordingly, the cited reference does not anticipate the claims.

B. Claims 1-12 and 15-42 are rejected under 35 U.S.C. § 102(e) as being anticipated by

U.S. Patent 6,656,684.

Claims 2, 24, 28, and 30 have been canceled without prejudice or disclaimer of the subject matter claimed therein. Thus, the rejection of claims 2, 24, 28, and 30 is deemed moot.

As stated above, claim 1 and its dependent claims are directed to a method of diagnosing cancer in a patient comprising assaying a sample of urine supernatant for the presence or absence of survivin. The cited U.S. Patent does not disclose a method of diagnosing cancer comprising assaying a sample of urine supernatant for the presence or absence of survivin. As stated in the Office Action, the cited U.S. Patent discloses contacting a mammalian tissue sample with a survivin-specific ligand for predicting the recurrence of a tumor or cancer. In contrast, the present invention is based on a safe, reliable, non-invasive screening method for detecting cancer, which does not require obtaining a tissue sample from a patient. A sample of urine supernatant recited in the present claims is distinct from the tissue sample disclosed in the cited patent. Accordingly, the cited reference does not anticipate the claimed invention.

Rejections of the Claims Under 35 U.S.C. § 103(a)

A. Claims 1-4, 6-10, 13-24, 28-32, 41, and 42 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Jouben-Steele *et al.* in view of Bio-Rad Laboratories Catalog 1998/99.

Claims 2, 24, 28, and 30 have been canceled without prejudice or disclaimer of the subject matter claimed therein. Thus, the rejection of claims 2, 24, 28, and 30 is deemed moot.

Claim 1, as amended, is directed to a method of diagnosing cancer in a patient comprising assaying a sample of urine supernatant for the presence or absence of survivin. Claim 17, as amended, is directed to a kit for diagnosis, prognosis, or monitoring cancer, comprising a container for collecting urine supernatant from a patient and an agent that detects the presence of survivin. Claims 2-13, 15-23, 25-27, 29, and 31-42 ultimately depend from claim 1 or 17.

The deficiencies of Jouben-Steele *et al.* have been discussed above. Briefly, Jouben-Steele *et al.* do not disclose assaying a sample of urine supernatant for the absence or presence of survivin for diagnosing, prognosing, or monitoring cancer in a patient. Likewise, the cited catalog of Bio-Rad Laboratories does not teach assaying a sample of urine supernatant for the absence or presence of survivin for diagnosing cancer and the cited catalog does not make up the

deficiencies of Jouben-Steele. Accordingly, one would not have reasonably expected to obtain the claimed invention by combining the two references and the cited references do not render the claimed invention obvious.

B. Claims 1-13 and 15-42 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Jouben Steele *et al.* in view of U.S. Patent 6,656,684.

Claims 2, 24, 28, and 30 have been canceled without prejudice or disclaimer of the subject matter claimed therein. Thus, the rejection of claims 2, 24, 28, and 30 is deemed moot.

Claim 1, as amended, is directed to a method of diagnosing cancer in a patient comprising assaying a sample of urine supernatant for the presence or absence of survivin. Claim 17, as amended, is directed to a kit for diagnosis, prognosis, or monitoring cancer, comprising a container for collecting urine supernatant from a patient and an agent that detects the presence of survivin. Claims 2-13, 15-23, 25-27, 29, and 31-42 ultimately depend from claim 1 or 17.

The deficiencies of Jouben-Steele *et al.* and the cited U.S. Patent have been discussed above. Neither of them discloses assaying a sample of urine supernatant for the presence or absence of survivin for diagnosing, prognosing, or monitoring cancer in a patient. Accordingly, one would not have reasonably expected to obtain the claimed invention by combining the two cited references, and the cited references do not render the claimed invention obvious.

C. Claims 1-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,656,684 in view of Bio-Rad Laboratories Catalog 1998/99.

Claims 2, 24, 28, and 30 have been canceled without prejudice or disclaimer of the subject matter claimed therein. Thus, the rejection of claims 2, 24, 28, and 30 is deemed moot.

Claim 1, as amended, is directed to a method of diagnosing cancer in a patient comprising assaying a sample of urine supernatant for the presence or absence of survivin. Claim 17, as amended, is directed to a kit for diagnosis, prognosis, or monitoring cancer, comprising a container for collecting urine supernatant from a patient and an agent that detects the presence of survivin. Claims 2-13, 15-23, 25-27, 29, and 31-42 ultimately depend from claim 1 or 17..

The deficiencies of the cited U.S. Patent and the Bio-Rad Laboratories Catalog have been discussed above. Neither of them discloses assaying a sample of urine supernatant for the presence or absence of survivin for diagnosing, prognosing, or monitoring cancer in a patient. Accordingly, one would not have reasonably expected to obtain the claimed invention by combining the two cited references, and the cited references do not render the claimed invention obvious.

Conclusion

The foregoing amendments and remarks are being made to place the application in condition for allowance. Applicants respectfully request entry of the amendments, reconsideration, and the timely allowance of the pending claims. A favorable action is awaited. Should the Examiner find that an interview would be helpful to further prosecution of this application, they are invited to telephone the undersigned at their convenience.

If there are any additional fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0310. If a fee is required for an extension of time under 37 C.F.R. §1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,
Morgan, Lewis & Bockius LLP

Sally P. Teng
Registration No. 45,397

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Morgan, Lewis & Bockius LLP
Customer No. **09629**
1111 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
Tel: 202-739-3000
Fax: 202-739-3001